said patient a therapeutically effective amount of a pharmaceutical aerosol formulation comprising a HFA propellant; a physiologically effective amount of the medicament; and a surfactant selected from the group consisting of a C_8-C_{16} fatty acid or salt thereof, a bile salt, a phospholipid, and an alkyl saccharide, wherein the ratio of surfactant to medicament is in the range of 1:50 to 1:0.2.

B2 cont'd

REMARKS

Claims 1-23, 25-31, 33, 34, and 37-45 are now pending in the application, claim 24 having been cancelled by the above amendment. Independent claims 1 and 37 have been amended to require a surfactant:medicament ratio of 1:50 to 1:0.2. These amendments are supported by original claim 24 as filed. No new matter has been added.

All pending claims are rejected under 35 U.S.C. § 102(b) as being anticipated by Akehurst et al. Applicants have amended the claims to require the presence of a substantial amount of surfactant: *i.e.*, enough to result in a ratio of surfactant to medicament of 1:50 to 1:0.2. Akehurst plainly does not teach or suggest this limitation. Akehurst is interested in **eliminating** surfactants from aerosol formulations (col. 2, lines 6-13), not in adding surfactants to a formulation in order to facilitate absorption of a medicament in the lower respiratory tract as taught in the present application. In fact, a critical

feature of Akehurst's formulations is that they be "substantially free of surfactants" (col. 2, line 26). Given this teaching of Akehurst, Applicants are unsure as to why this reference was cited as anticipating the claims as originally presented, all of which require the presence of a surfactant. Applicants speculate that the Examiner may have been relying on Akehurst's definition of formulations substantially free of surfactants as having "no significant amounts of surfactant, for example less than 0.0001% by weight of the medicament" (col. 2, lines 25-28). Since most of the original claims did not specify a lower limit for surfactant concentration, the Examiner may have felt that a formulation which contains "less than 0.0001% by weight" contains a trace amount and so technically fell within claims 1 and 37. While this seems to Applicants to be an overly-broad interpretation of Akehurst's teachings, Applicants have nevertheless addressed it by amending the claims to clarify that applicants' aerosol formulations must contain a significant amount of surfactant, as opposed to a trace amount: *i.e.*, a surfactant:medicament ratio of 1:50 to 1:0.2. As this range signifies an amount of surfactant corresponding to at least 2% of the weight of medicament (far above the 0.0001% maximum established in Akehurst), claims 1 and 37 are clearly not anticipated by Akehurst. It follows that claims 2-23, 25-31, 33, and 38-45, all of which directly or indirectly depend on claim 1 or 37, also are not anticipated by the cited reference.

CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested.

Please charge any fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

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